

## R E M A R K S

In the Office Action dated December 16, 2008, the Examiner stated at the top of page 3 that claims 27-36 and 63 were rejected under 35 U.S.C. §102(e) as being anticipated by Salo et al. The substantiation of this rejection, however, identifies many more claims than claims 27-36 and 63, and it appears that the Examiner intended to reject claims 27-43 and 47-63 as being anticipated by Salo et al.

Claims 44-46 were rejected under 35 U.S.C. §103(a) as being unpatentable over Salo et al. in view of Paul et al.

These rejections are respectfully traversed for the following reasons.

Previously, in response to the December 16, 2008 Office Action, Applicants submitted a Declaration under 37 C.F.R. §1.131 that Applicants submitted established a date of invention in Sweden (a WIPO country) that is at least as early as September 17, 2003. The Salo et al. reference has an effective date for use as prior art as of its United States filing date, which is November 7, 2003. Since Applicants' date of invention in Sweden predates this effective prior art date of the Salo et al. reference, Applicants submitted that the Salo et al. reference is not available as prior art against the subject matter of the present application.

In an Advisory Action dated April 6, 2009, the Examiner entered the aforementioned Declaration, but stated that the submission of the Declaration does not place the application in condition for allowance because the Examiner stated the Declaration is insufficient to establish priority of the entirety of the invention in terms of conception and reduction to practice, because the Examiner stated "Applicants' disclosure" (Applicants assume the Examiner intended to refer to the Invention Disclosure document that was attached as an exhibit to the Declaration) is "an

abstract concept and fails to demonstrate the elements of an implantable device necessary to achieve the idea as claimed. Particularly, many elements of the dependent claims also lack support in the Affidavit as filed. As the Affidavit appears to be a disclosure of an abstract idea, the reduction to practice requirement is not met.”

These conclusions on the part of the Examiner are respectfully traversed for the following reasons.

Applicants acknowledge that the Invention Disclosure document does not include all of Figures of the present application as originally filed, but Applicants submit that, at least as to the independent claims of the application, each and every claim limitation is clearly and unambiguously described in the original disclosure document in a manner that enables a person of ordinary skill in the field of designing implantable medical stimulation devices to make and use the invention.

The basic definition of “conception” that is currently in use today was established in *Megenthaler v. Scudder*, 11 App. D. C. 264, 1897 C.D. 724 (D.C. Cir. 1897) as follows:

The conception of the invention consists in the complete performance of the mental part of the inventive act. All that remains to be accomplished in order to perfect the act or instrument belongs to the department of construction, no invention. It is, therefore, the formation in the mind of the inventor of a definite and permanent idea of the complete and operative invention as it is therefore to be applied in practice that constitutes an available conception within the meaning of the patent law.

This definition established in the *Megenthaler* Decision was adopted and long used by the Court of Customs and Patent Appeals, and was subsequently adopted by the United States Court of Appeals for the Federal Circuit in numerous decisions, such as in *Sewall v. Walters*, 21 F.3d 411, 30 U.S.P.Q.2d 1356 (Fed. Cir. 1994).

As also stated in numerous decisions of the United States Court of Appeals for the Federal Circuit, an implication of the completeness requirement of the *Megenthaler* definition of conception is that a conception must include all the limitations or element of a patent claim or interference count, *Mycogen Plant Science, Inc. v. Monsanto Co.*, 252 F.3d 1306, 58 U.S.P.Q.2d 1891 (Fed. Cir. 2001, *reh'g. denied*, 261 F.3d 1345 59 U.S.P.Q.2d 1852 (Fed. Cir. 2001).

As to the standard to use for determining whether each and every claim limitation has been known to the inventor (i.e. in the mind of the inventor) as of the alleged date of conception, the United States Court of Appeals for the Federal Circuit has adopted the standard applied by the Court of Customs and Patent Appeals, which is to use the same type of evidence that is employed to determine whether the enablement requirement of 35 U.S.C. §112, first paragraph has been met. The Court of Customs and Patent Appeals stated in *Spero v. Ringold*, 377 F.2d 652, 660, 153 U.S.P.Q. 726, 732 (CCPA 1967) that

A priority of conception is established when the invention is made sufficiently plain to enable those skilled in the art to understand it ... Since the conception of an invention is a mental act known only to its originator, it follows that it must be proven by evidence showing what the inventor has disclosed to others, and what that disclosure means to one of ordinary skill in the art. In this light, that standard for approving conception is not essentially different from that required for proving reduction to practice or adequacy of support in a disclosure for a claim. In all of these cases, the proof of disclosure by the inventor must be interpreted in light of what it means to a person of ordinary skill in the art.

In *Loral Fairchild Corp. v. Victor Company of Japan Limited*, 931 F.Supp. 1014, 1029 (E.D. N.Y. 1966), *aff'd* 181 F.3d 1313, 50 U.S.P.Q.2d 1865 (Fed. Cir. 1999), *cert denied*, 528 U.S. 1075 (2000), Judge Rader of the United States Court of Appeals for the Federal Circuit, sitting by designation in the District Court, stated

Conception requires that an inventor have formed in his or her mind a definite and permanent idea of the complete and operative invention. ...The idea must be so clearly defined in the inventors' mind that only ordinary skill, without extensive research or experimentation, would be necessary to reduce the invention to practice.

Against these evidentiary requirements, it is clear that the disclosure documents attached to the Declaration under 37 C.F.R. §1.131 establish that the inventors conceived the subject matter of at least the independent claims of the present application before the effective prior art date of the Salo et al. reference. Clearly both disclosure documents explicitly describe "a center configured to interact with a heart to obtain information associated with functioning of the heart," by virtue of describing obtaining an IEGM signal. Moreover, both disclosure documents explicitly describe detecting a DHF state of the heart from this information, by determining, as a DHF parameter, a time duration of a predetermined phase of diastole of the heart. This is clearly indicated in the figures shown in each of the two Invention Disclosure documents.

Moreover, at the end of Section 3 of the first disclosure document, it is explicitly stated that the "surrogate" (i.e., the detected change in the deceleration time), can be used to optimize DHF pacing therapy or for optimizing pacemaker settings. This necessarily means that some type of signal indicative of the DHF state must be generated.

Therefore, the entirety of the subject matter of independent claims 27, 47 and 48 is clearly described in the two disclosure documents.

Moreover, with regard to a number of the dependent claims, the Examiner stated that the Salo et al. reference "inherently discloses" the subject matter of those dependent claims. Applicants respectfully submit the Examiner has not established

the relevant evidentiary standard for justifying an “inherency” rejection. It has long been held in the case law, however, that mere suppositions and allegations cannot support a finding of inherency. As stated by the Court of Customs and Patent Appeals more than 60 years ago in *Hansgrig v. Kimmer*, 102 F.2d 212, 40 U.S.P.Q. 665 (CCPA 1939):

Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.

This position has been reiterated many times by the United States Court of Appeals for the Federal Circuit. Moreover, the Federal Circuit has held that if some sort of intrinsic evidence is relied upon to establish inherency, this evidence “must make clear that the missing descriptive matter is *necessarily* present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill” (emphasis added), *Continental Can Co. v. Monsanto Co.*, 948 F.2d 1264 1267, 20 U.S.P.Q.2d 1746, 1749 (Fed. Cir. 1991).

There is no basis whatsoever in the Salo et al. disclosure, for example, with regard to the very detailed description of the calculations that are claimed in claims 28-32 and 49-53, or the subject matter of claims 41, 43, 62 or 63.

Applicants therefore submit that at least with regard to the independent claims and those dependent claims, the Salo et al. reference either is not available as prior art, or does not provide an anticipating disclosure.

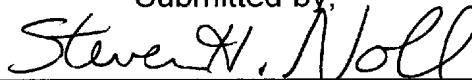
With regard to the remaining dependent claims that were rejected as being anticipated by Salo et al., as well as claims 44-46 that were rejected under 35 U.S.C. §103(a) based on Salo et al. and Paul et al., Applicants submit that those claims describe details that are easily discernable by, or where already well known to, those

of ordinary skill in the field of designing implantable stimulation devices, and therefore Applicants submit that those claims are entitled to the conception date that precedes the Salo et al. reference, for the same reasons discussed above with regard to the independent claims.

All claims of the application are therefore submitted to be entitled to a date of conception that predates the effective prior art date of the Salo et al. reference, and all claims of the application are therefore submitted to be in condition for allowance. Early reconsideration of the application is respectfully requested.

The Commissioner is hereby authorized to charge any additional fees which may be required, or to credit any overpayment to account No. 501519.

Submitted by,

 (Reg. 28,982)

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